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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth F. Buechler et al.

Title: METHOD FOR MONITORING THE STATUS OF ASSAY AND IMMUNOASSAY

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APPEAL BRIEF

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Sir:

Applicants (herein, "Appellants") hereby appeal the Final Rejection of claims 27, 28, and 93-128. This Appeal Brief is accompanied by a Notice of Appeal. The fee for this Appeal Brief (37 C.F.R. § 41.20(b)(2)) should not be done since it was paid for an earlier Appeal Brief filed December 19, 2002. If these fees are incorrect or if any additional fees are due in this regard, please charge or credit our Deposit Account No. 50-0872 for the appropriate amount.

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Real Party in Interest

The real party in interest in this appeal is Biosite Incorporated (formerly Biosite Diagnostics, Inc.), which is the assignee of the present application.

Related Appeals and Interferences

No related appeals or interferences are pending.

Status of Claims

Claims 27, 28, and 93-128 are pending in the application, with claims 29-92 having been cancelled. For the convenience of the Board, the pending claims are presented in Appendix A of this Brief.

The status of Claims 113-128 is uncertain. The "Office Action Summary" from May 5, 2005, indicates that these claims have been withdrawn from consideration. Despite this, the Examiner proceeds in the body of the Office Action to examine Claims 113-128 on the merits (this also occurred in the Office Action of November 19, 2003). These claims remain pending in the application, but are indicated in Appendix A of this Brief as being withdrawn from examination. Nevertheless, Appellants have included Claims 113-128 in the remarks presented herein, based on the inclusion of these claims in the rejections.

Claims 27, 28, and 93-128 stand finally rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Claims 27, 28, and 93-128 stand finally rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement.

Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen *et al.*, U.S. Patent 5,132,097.

Claims 95 and 117 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen et al., U.S. Patent 5,132,097, in further view of Slovacek *et al.*, U.S. Patent 5,242,837.

Claims 28, 101, 102, 104, 107, 108, 127, and 128 stand finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen et al., U.S. Patent 5,132,097, in further view of Foster *et al.*, U.S. Patent 4,444,879.

Claim 103 stands finally rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Buechler, U.S. Patent 5,458,852, in view of Van Deusen et al., U.S. Patent 5,132,097, in further view of Slovacek *et al.*, U.S. Patent 5,242,837, and Foster *et al.*, U.S. Patent 4,444,879.

According to the Examiner, Claims 97, 98, 105, 106, 119, and 120 would be allowable if written in independent form.

Status of Amendments

No amendments are outstanding.

Summary of Claimed Subject Matter

The claimed subject matter relates to assay devices for determining the presence or amount of an analyte of interest in a sample, and kits containing such devices. The devices of the present invention comprise, *inter alia*, the following elements:

(a) an assay device comprising:

(i) a reaction chamber comprising an optically detectable label, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least

one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

Analyte assays have become increasingly important in clinical settings. Because such assays must often be performed outside of a well controlled laboratory setting and by non-expert personnel (*e.g.*, in an emergency room setting by emergency medical technicians), the ability to provide simple assay devices that perform in a predictable fashion is at a premium. Specification, page 1, line 21, through page 2, line 17. Prior to the present invention, predictability in such simple devices could be problematic, due to variations in conditions of device manufacture, in the sample matrix, and in environmental conditions under which the device is used. Specification, page 10, lines 6-15.

One issue raised in performing an assay is determining whether a low signal from the analyte in the assay results from: 1) a completed assay where the low signal accurately reflects a low level of analyte in the test sample, or 2) an incomplete assay where the low signal is an underepresentation of the level of analyte in the test sample.

In an effort to address these issues of predictability, the present invention discloses for the first time the use of independent assay controls (IAC's) in assay devices. Specification, page 32, lines 3-4. IACs, including the "timing zone" signals of the present claims, provide control signals that do not depend upon assay results for the analyte of interest, but that are dependent upon the non-analyte characteristics of the sample being analyzed and the particular characteristics of the individual assay device being used. *See, e.g.*, specification, page 31, lines 24-29. The IAC results are "independent" of the analyte assay, meaning the signal from the IAC is not a function of the analyte determination. As such, IACs provide a predictable signal that may be used to determine one or more parameters of the assay being performed in the device.

In the present claims, the invention features an apparatus configured for "measuring progress and time of completion of an assay for an analyte of interest," and the IAC used for this purpose is a signal obtained from a "timing zone." As for all IACs described in the specification, the timing zone provides a signal that is "predictable within a range, set by the manufacturer." Specification, page 31, line 25. This timing function "allows the instrument to judge when the assay process is complete." Specification, page 40, lines 18-19.

In the rejected claims, a "timing zone" is a zone within an assay device that is separate from the assay zone(s) that bind the analyte(s) of interest. The "timing zone" and the "optical component" are interrelated, in that the optical component is "configured to detect" an optical signal generated from label in the timing zone and generate an electronic signal in response. The electronic signal is then used by a "signal processor" that is "configured to receive" the electronic signal and to determine the progress and time of completion of the assay(s) from the signals received. Thus, the signal generated from the timing zone provides a measurement of assay progress and completion that is independent of the assay for the analyte of interest.

Grounds for Rejection to be Reviewed on Appeal

1. The rejection of Claims 27, 28, and 93-128 for being indefinite under 35 U.S.C. §112, second paragraph for use of the term "timing zone."

2. The rejection of Claims 27, 28, and 93-128 for failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph for use of the phrase "timing zone separated from the assay zone."

3. The rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 as being unpatentable under 35 U.S.C. §103(a) over Buechler, U.S. Patent 5,458,852, in view of Van Deusen *et al.*, U.S. Patent 5,132,097.

4. The rejection of Claims 95 and 117 as being unpatentable under 35 U.S.C. §103(a) over Buechler, in view of Van Deusen et al., in further view of Slovacek *et al.*, U.S. Patent 5,242,837.

5. The rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 as being unpatentable under 35 U.S.C. §103(a) over Buechler, in view of Van Deusen et al., in further view of Foster *et al.*, U.S. Patent 4,444,879.

6. The rejection of Claim 103 as being unpatentable under 35 U.S.C. §103(a) over Buechler, in view of Van Deusen et al., in further view of Slovacek *et al.* and Foster *et al.*, U.S. Patent 4,444,879.

Argument

1. Rejection of Claims 27, 28, and 93-128 under 35 U.S.C. §112, second paragraph (definiteness)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of indefiniteness for the term "timing zone" under 35 U.S.C. §112, second paragraph. In the rejection, the Examiner first isolates the term "timing zone" from any context provided by both the specification and the claims themselves, setting up an analysis that is devoid of any meaningful definiteness inquiry, which requires that one interpret the claims as a whole and in the light of the specification. After divorcing the term "timing zone" from all context, the Examiner then alleges that the term "timing zone" is somehow a "relative term," and that it is unclear how the various elements of the claim relate to one another. However, when the claims are properly analyzed, the definiteness standard is met. Accordingly, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed.

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 25 F.3d 1566, 1576, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). Recognizing that the English language is not always precise, the settled law has established that the essential inquiry in a definiteness analysis is whether the claims set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.,* MPEP § 2173.02; *see also, Miles Laboratories, Inc. v. Shandon, Inc.*, 997 F.2d 870, 875, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added). Definiteness is not analyzed in a vacuum, but in light of the content of the specification, and with the knowledge available to the skilled artisan.

As discussed above, the present claims refer to devices for measuring the presence or amount of at least one analyte. The "timing zone" referred to in the instant claims is one embodiment of an "independent assay control" (IAC). As described in the specification, IACs are control measurements that provide a signal that is generated in connection with, but that is independent of, the signal obtained from the assay for the analyte of interest.

As described in the instant specification, *e.g.*, beginning on page 73, section entitled "*Use of the Timing Signal to Detect Assay Completion of Immunoassay Devices*," the phrase "timing zone" refers to a zone within an assay device where a signal is detected for use in determining if the assay for the analyte of interest has run to completion. Methods and devices for determining the progress and time of completion of assays using a signal obtained from such a "timing zone" are described in detail in the instant specification, *e.g.*, on page 13, line 7, through page 14, line 15; page 40, line 9, through page 42, line 23; page 70, line 15, through page 71, line 11; and page 73, line 6, through page 75, line 30.

In full agreement with the specification's discussion of what is meant by a "timing zone," the rejected claims describe an apparatus for measuring progress and time of completion of an assay for an analyte comprising the following elements (from Claim 27):

> (i) an assay device comprising
>
> a reaction chamber comprising an optically detectable label; and
>
> at least one diagnostic lane comprising at least one assay zone configured to bind the analyte of interest, and at least one timing zone separate from the assay zone;
>
> (ii) an optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response; and
>
> (iii) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

Thus, according to the literal language of the rejected claims, (i) a timing zone is a zone within an assay device that is separate from the assay zone(s) that bind the analyte(s) of interest; and (ii) from the timing zone, a signal is generated from a label within the assay device, the signal is then used by a signal processor to determine the progress and time of completion of the assay(s) for the analyte(s) of interest. Considering the literal language of the claims, and the extensive teachings in the instant specification concerning the design and use of timing zones, Appellants respectfully submit that the skilled artisan is reasonably apprised of the scope of the

claims with regard to the "timing zone" recited in the claims. As noted above, it is well settled that 35 U.S.C. § 112, second paragraph, demands no more.

Despite this clear description of the claimed subject matter, the Examiner asserts that the phrase "timing zone" should be considered a "relative term." *See,* Office Action mailed May 5, 2005, page 3. The reasoning given for this is that "[t]here is no requirement for an assay zone and a separate 'timing zone' or a 'timing zone' monitoring a measurable signal that is independent of the analyte." *Id.*, page 4. Since that is precisely what the claims literally recite (i.e., ". . . timing zone separate from the assay zone . . ."), the Examiner's rationale for the conclusion cannot be understood. The Examiner's conclusion is also at odds with the specification which, for example, describes measuring signals from "detection zones" (page 70, line 28), and determining a signal from a "timing zone" that is separate from any of these detection zones (page 71, lines 3-4). In short, the Examiner has provided no meaningful explanation for why the term "timing zone" is "relative," and what it might be relative to. It is respectfully submitted that the Examiner's remarks, which interpret the term "timing zone" unfettered by any context, are at odds with the requirement that the claims be interpreted in the light of the specification and by viewing the claim as a whole. *See, e.g.*, MPEP § 2173.02.

The Examiner further argues that the rejected claims are indefinite "because the interaction of the timing zone is unclear" (sic). Office Action mailed May 5, 2005, page 3. Specifically, the Examiner appears to believe that the timing zone must be located downstream from the assay zone(s), and that the timing zone must somehow bind to a label. *Id.* Appellants respectfully submit that this is simply incorrect.

No particular relationship between the assay zone(s) and the timing zone is required, either by the claims or by the specification. For example, the skilled artisan would understand that the timing zone may be placed at the distal end of the diagnostic lane (described as a preferred embodiment of the invention; *See, e.g.*, specification, page 41, lines 11-15). But the timing zone might also be placed parallel to the assay zone, or may even precede the assay zone. If made necessary by positioning of the timing zone in the device, the criteria for a measurement at the timing zone that defines assay completion may be derived empirically. *See, e.g.*,

specification, page 41, lines 22-23. Why such breadth should somehow render the claim indefinite is unclear.

Likewise, the Examiner's assertion that "the label does not clearly bind to either of the zones to produce a detectable product" (Office Action mailed May 5, 2005, page 3) is not relevant to the definiteness of the claims, and fails to consider the extensive teachings of the specification on the subject. Neither the claims nor the specification require that the label used to generate a signal at the timing zone be bound to the timing zone at the time. For example, while binding of the label to the timing zone is one embodiment of the present invention, a signal may also be generated from label flowing *through* the timing zone. *See, e.g.*, specification, page 71, lines 4-6.

Finally, Appellants note that the rejection is inconsistent with the Examiner's statement that Claims 97 and 98 are allowable if written in independent form. These claims, which depend from independent Claim 27, only further limit Claim 27 by reciting that the label used at the timing zone binds to the timing zone. These claims do not cure any deficiencies alleged by the Examiner except the final assertion that "the label does not clearly bind to either of the zones to produce a detectable product." The fact that the Examiner believes that such claims should be allowable only serves to underscore the fact that the rejection is not founded upon the proper standard by which definiteness is judged.

Appellants respectfully submit that, in a proper analysis, the phrase "timing zone" should not be interpreted in a vacuum as the Examiner has apparently done, but rather in light of the extensive teachings in the instant specification and from the point of view of one possessing the ordinary level of skill in the art. The clear interrelation of the optical component and the signal processor with the timing zone in the claims, together with the teachings of the specification, provide the necessary context to reasonably understand the scope of the claims. In contrast, the Examiner has failed to perform the required definiteness analysis in a meaningful fashion. Because the definiteness requirement of 35 U.S.C. § 112, second paragraph, has been met, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed.

2. Rejection of Claims 27, 28, and 93-128 under 35 U.S.C. §112, first paragraph (written description)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of a lack of written description under 35 U.S.C. §112, first paragraph. The rejection is predicated on a bare allegation that the specification "does not show support" for "an apparatus having at least one timing zone separated from the assay zone." Office Action mailed May 5, 2005, page 4. Because, as discussed above, the Examiner is clearly incorrect in this allegation, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed

The proper standard for determining compliance with the written description requirement of 35 U.S.C. § 112, first paragraph, is whether the specification reasonably conveys to the skilled artisan that the inventor was in possession of the claimed invention as of the filing date. *See* MPEP § 2163.02 (citing *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 USPQ 177, 179 (Fed. Cir. 1985)). The subject matter of the claimed invention need not be described literally in the specification in order to satisfy the requirements of 35 U.S.C. § 112, first paragraph. *Id.* In a careful analysis of the written description requirement provided by Patent and Trademark Office in its *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1, "Written Description" Requirement*, it is stated that an adequate written description "may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention." 66 Fed. Reg. 1099, 1105 (2001) (emphasis added).

In describing the claimed invention, the specification states that the progress and time of completion of an assay, a timing zone signal is measured at "a discrete zone" in the diagnostic lane. *See, e.g.*, specification, page 13, lines 11-15; page 41, lines 6-10; and page 42, lines 2-4. The specification also states that the assay measurement may be made in one zone, and the IAC signal (*e.g.*, the timing zone signal) measured in another zone. *See, e.g.*, specification, page 12, line 30, through page 13, line 21. The specification also provides an example where the timing zone is "downstream of the last detection zone"; thus, in this example, the timing zone is separate from the assay zone. *See, e.g.*, specification, page 71, lines 2-4.

In the face of this seemingly clear and unmistakable support for "an apparatus having at least one timing zone separated from the assay zone," the Examiner provides the following analysis of whether the claims meet the written description standard: "The disclosure does not show support form (sic) this limitation." Office Action mailed May 5, 2005, page 4. The Examiner points to page 73, lines 13-25 of the specification, alleging that this particular section of the specification "appears to teach a 'timing signal zone' or 'timing zone' along the entire diagnostic lane wherein a signal is measured every ten seconds by window advancement over the discrete zones of the device." Office Action mailed May 5, 2005, page 5. But whether or not the Examiner is correct (and nothing in the cited section indicates that timing zones and assay zones are not distinct locations), the cited section does not negate those portions of the specification that provide explicit support for the claims as written. The Examiner's failure to consider the specification as a whole, or explain why the specification fails to reasonably convey to the skilled artisan that the inventor was in possession of the claimed invention, renders the rejection fatally flawed.

Moreover, Appellants note that the rejection is inconsistent with the Examiner's statement that Claims 97 and 98 are allowable if written in independent form. As discussed above, these claims only further limit independent Claim 27 by reciting that the label used at the timing zone bind to the timing zone. These claims should not have been allowable if the Examiner's rationale for the written description rejection were sound. Nevertheless, the Examiner believes that such claims should be allowable.

In view of the clear teachings in the instant specification, Appellants respectfully submit that the skilled artisan is reasonably informed that Appellants were in possession of "an apparatus having at least one timing zone separated from the assay zone," the only written description basis on which the Examiner objects to the claims. Because the written description requirement of 35 U.S.C. § 112, first paragraph, has been met in this regard, Appellants respectfully request that the rejection of Claims 27, 28, and 93-128 be withdrawn or reversed.

3. Rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 over Buechler, U.S. Patent 5,458,852, in view of Van Deusen *et al.*, U.S. Patent 5,132,097. The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner has failed to consider various claim elements in the rejection, there is no motivation established by the Examiner to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 be withdrawn or reversed.

To establish a *prima facie* case of obviousness, three criteria must be met; there must be some motivation or suggestion, either in the cited publications or in knowledge available to one skilled in the art, to modify or combine the cited publications; there must be a reasonable expectation of success in combining the publications to achieve the claimed invention; and the publications must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); MPEP § 2142. In analyzing obviousness, the Court of Appeals for the Federal Circuit has repeatedly cautioned that:

> [t]he factual inquiry... must be based upon objective evidence of record.... [T]he best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.... [P]articular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.

In re Sang-Su Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (internal citations omitted).

The claimed apparatus for measuring the progress and time of completion of an assay for an analyte comprise, *inter alia*, the following elements (from Claim 27):

(i) an assay device comprising

a reaction chamber comprising an optically detectable label; and

> at least one diagnostic lane comprising at least one assay zone configured to bind the analyte of interest, and at least one timing zone separate from the assay zone;
>
> (ii) an optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response; and
>
> (iii) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

The Examiner begins the obviousness analysis with a flawed perspective of the primary Buechler '852 patent, stating that this patent discloses "a time gate for measuring the reaction in a given period of time." Office Action mailed May 5, 2005, page 7 (emphasis added). A definition of a "time gate" in the '852 patent readily contradicts the Examiner's assertion.

Time Gate

> Referring to FIG. 1a, the time gate 5 holds the reaction mixture in the reaction chamber 4 for a given period of time. The concept of the time gate is that a predominantly aqueous solution cannot pass through a hydrophobic zone until the hydrophobic zone is made hydrophilic. Furthermore, the hydrophobic zone is made hydrophilic by a component in the aqueous solution.

'852 patent, Column 7, lines 41-47 (emphasis added). As is made clear by this definition, the "time gate" of the '852 patent is not involved in *measuring* any reaction, contrary to the Examiner's position; rather, it is a device to *delay* flow across a hydrophobic zone until that zone is made hydrophilic. There is no signal generated from this "time gate;" as such, there is no progress of an assay and its time of completion determined from a signal from the "time gate." Also, there is no processor configured to receive and process such a signal.

The Examiner also errs in ignoring the "configured to" language of the present claims with respect to question of whether the '852 patent teaches two additional elements of the present claims – the "optical component configured to detect an optical signal generated from the timing zone and generate an electronic signal in response" and the "signal processor configured to read the electronic signal and determine the progress of the assay and its time of completion."

By simply ignoring the "configured to" language of the claims, the Examiner concludes that an optical component and signal processor of the '852 patent may be reduced to any and all optical components, and any and all processors, no matter what purpose each serves and how they are configured in a device. *See, e.g.*, Office Action mailed May 5, 2005, page 13 ("the features upon which applicant relies (i.e., structural elements reading on 'configured to') are not recited in the rejected claim(s)").

Appellants respectfully submit that the Examiner is incorrect that the "configured to" language in the present claims is mere surplussage that may be ignored in rejecting the claims. Instead, the recitation of elements "configured to" one another is common in patents and represents a structural limitation that must be considered. *See, e.g., Ex parte Boudry et al.*, Appeal No. 2000-1978, 2001 WL 1176515 at *3 ("As set forth previously, the limitation that the adhesive be configured to contact the wearer's body in use... is a structural limitation"); see also, *Ex parte Yagihashi and Sato*, Appeal No. 2004-2289, 2005 WL 1181897 at *3 (reversing a rejection under 35 U.S.C. §103 of a claim reciting "a purchaser terminal configured to enable a user to view..."), *Ex parte Rosenhain*, Appeal No. 97-0672, 1997 WL 1909599 at *2 (reversing a rejection under 35 U.S.C. §103 of a claim reciting "at least one gripping member configured to engage and removably hold a utensil"); the latter two decisions, while not binding precedent, are cited here as persuasive authority (copies attached in Appendix B).

Appellants reiterate that the '852 patent does not disclose or suggest any optical component configured to detect an optical signal generated from its "time gate" and generate an electronic signal in response, since the '852 patent does not consider the "time gate" to be an element from which a signal either can or should be determined. Furthermore, because there is no signal to be generated from this "time gate," no processor is configured to determine the progress of an assay and its time of completion from a signal from the "time gate." In short, there is no correspondence between the "time gate" of the '852 patent and the "timing zone" of the present claims and, consequently, the optical component and processor of the '852 patent are not appropriately configured.

The Examiner continues the rejection by further mischaracterizing the teachings of the'852 patent. For example, the Examiner states that "the rate of change is monitored by the

flow of reagents through the porous member." Office Action mailed May 5, 2005, page 7. The Examiner refers to column 18, lines 2-8 of the '852 patent to support this assertion. However, the passage does not support the Examiner's conclusion. In fact, it states something completely different -- that fluid control means like a "time gate" can be used to *control* the rate of flow, not to *monitor* the rate of flow, as the Examiner apparently believes.

Then, referring to possible modifications of devices disclosed in the '852 patent, the Examiner states that "the label (signal development element) does not appreciably bind to any reagent in the assay device but could be designed to indirectly cause a visually or instrumentally detectable signal as a result of the assay process." Office Action mailed May 5, 2005, page 7 (emphasis added). Appellants respectfully submit that the mere fact that the devices of the primary '852 patent *could be designed* to meet some limitation of the present claims does not establish that such devices meet the requirements of the instant claims, or provide a motivation to modify the devices of the cited publication. To establish a motivation to modify the prior art, the Examiner must provide some motivation or suggestion, either in the cited references or in knowledge available to the ordinarily skilled artisan to do so (*see, e.g.*, MPEP §2143), rather than simply stating that such a modification *could be* made.

Furthermore, the Examiner's reliance on the secondary Van deusen *et al.* '097 patent solely for the alleged disclosure of "an optical signal detector and signal processor" (Paper No. 24, page 12) fails to fill the gaps from the initial reference. Simply combining these publications to place an optical signal detector and signal processor in a device with a "time gate" as defined in the '852 patent fails to disclose all of the limitations of the instant claims. There is no teaching cited to configure the optical signal detector and signal processor in the manner claimed. No motivation has been established to do so, since the Examiner apparently believes the requirement for configuration required by the claims can be ignored.

The publications of record, whether considered separately or together, do not disclose or suggest that any signal should be obtained from a discrete timing zone or that a signal processor should be used to determine the progress and time of completion of an assay from that signal. Furthermore, the fundamental elements of an obviousness rejection -- a teaching or suggestion of each element of the claims and a motivation to modify the cited publications to provide the invention as claimed -- are lacking from the Examiner's asserted *prima facie* case.

Because the publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims, and because no motivation has been established to modify the cited publications to provide each of the elements of the present claims, Appellants respectfully submit that no *prima facie* case of obviousness has been established. Accordingly, Appellants request that the rejection of Claims 27, 93, 94, 96, 99-100, 109-116, 118, and 121-126 under 35 U.S.C. § 103(a) be withdrawn or reversed.

4. Rejection of Claims 95 and 117 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 95 and 117 over the Buechler '852 patent, in view of the Van Deusen *et al.* the '097 patent, and a new secondary reference -- Slovacek *et al.*, U.S. Patent 5,242,837.

Because the new secondary publication is cited only for the disclosure of "a fluorometer as a useful optical detector" (Office Action mailed May 5, 2005, page 8), the fatal flaws in the Examiner's rejection based on the '852 and '097 patents remain fatal flaws in this rejection. Specifically, the rejection is flawed because (i) it is founded upon multiple mischaracterizations of the teachings of the '852 patent; (ii) the Examiner has disregarded elements of the claims which recite how elements are "coupled to" one another; and (iii) it relies on the assertion that devices in the '852 patent "could be designed" to practice the claimed invention.

The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner ignores various claim elements in the rejection, there is no motivation established to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claims 95 and 117 be withdrawn or reversed.

5. Rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 over the Buechler '852 patent, in view of the Van Deusen *et al.* '097 patent and another new secondary publication -- Foster *et al.*, U.S. Patent 4,444,879.

Because the new secondary publication is cited only for the disclosure of assays in kit form (Office Action mailed May 5, 2005, page 9), the fatal flaws in the Examiner's rejection based on the '852 and '097 patents remain fatal flaws in this rejection. Specifically, the rejection is flawed because (i) it is founded upon multiple mischaracterizations of the teachings of the '852 patent; (ii) the Examiner has disregarded elements of the claims which recite how elements are "coupled to" one another; and (iii) it relies on the assertion that devices in the '852 patent "could be designed" to practice the claimed invention.

The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner ignores various claim elements in the rejection, there is no motivation established to modify the cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 be withdrawn or reversed.

6. Rejection of Claim 103 under 35 U.S.C. §103(a)

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 for the rejection of Claims 28, 101, 102, 104, 107, 108, 127, and 128 over the Buechler '852 patent, in view of the Van Deusen *et al.* '097 patent, the Slovacek *et al.* '837 patent, and the Foster *et al.* '879 patent.

This last rejection simply combines the alleged disclosure of "a fluorometer as a useful optical detector" from the '837 patent and the alleged disclosure of assays in kit form from the '879 patent, with the flawed rejection based on the '852 and '097 patents. Again, those flaws remain fatal flaws in this rejection. Specifically, the rejection is flawed because (i) it is founded upon multiple mischaracterizations of the teachings of the '852 patent; (ii) the Examiner has disregarded elements of the claims which recite how elements are "coupled to" one another; and (iii) it relies on the assertion that devices in the '852 patent "could be designed" to practice the claimed invention.

The publications cited in the rejection, considered alone or together, do not teach or suggest each and every element of the present claims. Additionally, because the Examiner ignores various claim elements in the rejection, there is no motivation established to modify the

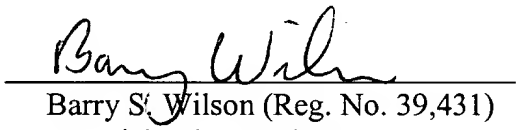
cited publications to provide each of the elements of the present claims. Appellants therefore respectfully request that the rejection of Claim 103 be withdrawn or reversed.

Conclusion

For the reasons discussed above, Appellants respectfully submit that Claims 27, 28, and 93-128 are in condition for allowance, and respectfully request that the rejections be withdrawn or reversed, and that the claims be allowed to issue. Appellants further request that the Claims status of Claims 113-128 be resolved and, fully considered.

Respectfully submitted,

Date: August 4, 2005

By: 
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Appendix A: Text of the Claims Involved in the Appeal

Claims 1-26 (Cancelled)

27. (Previously amended) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber comprising an optically detectable label, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid is added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

28. (Previously presented) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 27.

Claims 29-92 (Cancelled)

93. (Previously amended) The apparatus of claim 27, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting

dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

94. (Previously presented) The apparatus of claim 27, wherein the assay device is an immunoassay device.

95. (Previously presented) The apparatus of claim 27, wherein the optical component is a fluorometer.

96. (Previously presented) The apparatus of claim 27, wherein the reaction chamber and said at least one diagnostic lane are each within a capillary space.

97. (Previously presented) The apparatus of claim 27, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

98. (Previously presented) The apparatus of claim 97, wherein one or both of said first and second members of the binding pair is an antibody.

99. (Previously presented) The apparatus of claim 27, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

100. (Previously presented) The apparatus of claim 27, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

101. (Previously presented) The kit of claim 28, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

102. (Previously presented) The kit of claim 28, wherein the assay device is an immunoassay device.

103. (Previously presented) The kit of claim 28, wherein the optical component is a fluorometer.

104. (Previously presented) The kit of claim 28, wherein the reaction chamber and diagnostic lane are each within a capillary space.

105. (Previously presented) The kit of claim 28, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

106. (Previously presented) The kit of claim 105, wherein one or both of said first and second members of the binding pair is an antibody.

107. (Previously presented) The kit of claim 28, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

108. (Previously presented) The kit of claim 28, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

109. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone and said at least one timing zone are located in the same diagnostic lane.

110. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone and said at least one timing zone are located in a separate diagnostic lane.

111. (Previously presented) The apparatus of claim 27, wherein a surface of said at least one timing zone is configured to bind said detectable label.

112. (Previously presented) The apparatus of claim 27, wherein said at least one assay zone does not appreciably bind said detectable label.

113. (Withdrawn) An apparatus for measuring progress and time of completion of an assay for an analyte, comprising:

(a) an assay device comprising:

(i) a reaction chamber, and

(ii) at least one diagnostic lane comprising at least one assay zone configured to bind said analyte and at least one timing zone separate from the assay zone, wherein said diagnostic lane is in fluid communication with said reaction chamber, and wherein, when fluid and a detectable label are added to said reaction chamber, said detectable label flows with said fluid to said at least one diagnostic lane to contact said at least one timing zone;

(b) an optical component configured to detect an optical signal generated from said label in said at least one timing zone and generate an electronic signal in response; and

(c) a signal processor configured to receive said electronic signal and to determine said progress and time of completion of said assay for said analyte in said assay device from at least one parameter selected from the group consisting of a rate of change of the amount of said electronic signal and an amount of said electronic signal.

114. (Withdrawn) The apparatus of claim 113, wherein said apparatus further comprises said detectable label.

115. (Withdrawn) The apparatus of claim 114, wherein said label is selected from the group of molecules consisting of dye, fluorescence emitting dye, chemiluminescence emitting dye, infrared emitting dye, colloidal sol, molecule that generates an electrical signal, molecule that generates a magnetic signal, molecule that generates and electrical and magnetic signal, and enzyme.

116. (Withdrawn) The apparatus of claim 113, wherein the assay device is an immunoassay device.

117. (Withdrawn) The apparatus of claim 113, wherein the optical component is a fluorometer.

118. (Withdrawn) The apparatus of claim 113, wherein the reaction chamber and said at least one diagnostic lane are each within a capillary space.

119. (Withdrawn) The apparatus of claim 113, wherein the label is attached to a first member of a binding pair that binds to a second member of the binding pair that is bound to said at least one timing zone of said at least one diagnostic lane.

120. (Withdrawn) The apparatus of claim 119, wherein one or both of said first and second members of the binding pair is an antibody.

121. (Withdrawn) The apparatus of claim 113, wherein said signal processor determines the progress and time of completion of said assay in said device from the rate of change of the amount of signal.

122. (Withdrawn) The apparatus of claim 113, wherein said signal processor determines the progress and time of completion of said assay in said device from the absolute amount of signal.

123. (Withdrawn) The apparatus of claim 113, wherein said at least one assay zone and said at least one timing zone are located in the same diagnostic lane.

124. (Withdrawn) The apparatus of claim 113, wherein said at least one assay zone and said at least one timing zone are located in a separate diagnostic lane.

125. (Withdrawn) The apparatus of claim 113, wherein a surface of said at least one timing zone is configured to bind said detectable label.

126. (Withdrawn) The apparatus of claim 113, wherein said at least one assay zone does not appreciably bind said detectable label.

127. (Withdrawn) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 113.

128. (Withdrawn) A kit for measuring progress and time of completion of an assay for an analyte, comprising:

(a) at least one set of instructions for measuring said progress and time of completion; and

(b) an apparatus according to claim 114.

Appendix B: Evidence Appendix

1. Buechler, U.S. Patent 5,458,852, cited by the Examiner in Office Action mailed August 24, 2001

2. Van Deusen *et al.*, U.S. Patent 5,132,097, cited by the Examiner in Office Action mailed August 24, 2001

3. Slovacek *et al.*, U.S. Patent 5,242,837, cited by the Examiner in Office Action mailed August 24, 2001

4. Foster *et al.*, U.S. Patent 4,444,879, cited by the Examiner in Office Action mailed November 24, 2003

5. *Ex parte Boudry et al.*, Appeal No. 2000-1978, 2001 WL 1176515

6. *Ex parte Yagihashi and Sato*, Appeal No. 2004-2289, 2005 WL 1181897

7. *Ex parte Rosenhain*, Appeal No. 97-0672, 1997 WL 1909599

2001 WL 1176515 (Bd.Pat.App & Interf.)
(Cite as: 2001 WL 1176515 (Bd.Pat.App & Interf.))

*1

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE KRISTINA MICHELLE BOUDRY ET AL.
Appeal No. 2000-1978
Application No. 08/898,905

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

JEFFREY B. CURTIN

KIMBERLY CLARK WORLDWIDE INC

401 NORTH LAKE STREET

NEENAH, WI 54957-0349

Before CALVERT, McQUADE, and NASE

Administrative Patent Judges.

NASE

Administrative Patent Judge.

ON BRIEF

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 to 31, which are all of the claims pending in this application.

We REVERSE.

BACKGROUND

The appellants' invention relates to a disposable absorbent article having an improved fastenability about the waist of a wearer (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Le Bolt	2,649,858	Aug. 25, 1953
Polski	5,066,289	Nov. 19, 1991
Takemoto	5,071,415	Dec. 10, 1991

Claims 19 to 23 and 29 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Takemoto.

Claims 19 and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Le Bolt.

Claims 19 to 23 and 31 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Polski.

Claims 1 to 9, 11, 12, 17, 18, 24 to 28 and 30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Takemoto.

Claims 10 and 13 to 16 stand rejected under 35 U.S.C. § 103 as being unpatentable over Takemoto.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the answer (Paper No. 18, mailed September 13, 1999) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 17, filed June 28, 1999) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The anticipation rejections based upon Takemoto

We will not sustain the rejection of claims 1 to 9, 11, 12 and 17 to 30 under 35 U.S.C. § 102(b) as being anticipated by Takemoto.

*2 To support a rejection of a claim under 35 U.S.C. § 102(b), it must be shown that each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference. See Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984).

Claims 1 to 9, 11, 12 and 17 to 30 are drawn to an absorbent article or diaper comprising, inter alia, an outer cover; a bodyside liner; an absorbent core located between the outer cover and the bodyside liner; and an adhesive located on a bodyfacing surface of the absorbent article or diaper wherein the adhesive is configured to contact a wearer's body during use to at least temporarily secure the bodyfacing surface of the absorbent article or diaper directly to the wearer's body.

Takemoto discloses an adhesive system for releasably fastening or securing superposed portions of a disposable diaper or other articles. Takemoto teaches (column 3, lines 4-11) that disposable diapers are generally of a three-piece structure: an inner liner or so-called top sheet of a non-woven material such as polyethylene, polypropylene, a polyester and the like; an outer polyolefin liner or so-called back sheet; and, sandwiched therebetween, the porous, absorbent material, generally referred to in the art as "fluff pulp", "wood fluff", or simply as "pulp". The closure system of Takemoto is shown in Figures 1-3 to comprise a pair of adhesive patches 24 secured to the inner surface 20 adjacent opposed edges of end portion 12. Patch 24 consists essentially of a sheet material 26 coated on either side with adhesive layers 28, 30. Adhesive layer 28 is a permanent adhesive

adapted to secure the patch to porous material 20; while adhesive layer 30 is a repositionable adhesive adapted to releasably engage the other plastic liner 22 adjacent end portion 14 when the diaper is folded into place on the body.

The appellants argue (brief, pp. 5-6 and 10-11) that Takemoto does not disclose a diaper or absorbent article which includes an adhesive which is configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper or absorbent article directly to the wearer's body. We agree. Additionally, we agree with the appellants that the limitation that the adhesive be configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper or absorbent article directly to the wearer's body is a structural limitation in that it requires placement of the adhesive in a location on the bodyfacing surface of the diaper or absorbent article such that it contacts the wearer's body when the diaper or absorbent article is in use (i.e., on the wearer). Clearly, when Takemoto's diaper is in use, the adhesive patches 24 contact the plastic liner 22 adjacent end portion 14, not the wearer's body. Accordingly, Takemoto's adhesive patches 24 are not configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body.

*3 For the reasons set forth above all the limitations of claims 1 to 9, 11, 12 and 17 to 30 are not disclosed in Takemoto, consequently, the decision of the examiner to reject claims 1 to 9, 11, 12 and 17 to 30 under 35 U.S.C. § 102(b) as being anticipated by Takemoto is reversed.

The anticipation rejection based upon Le Bolt

We will not sustain the rejection of claims 19 and 31 under 35 U.S.C. § 102(b) as being anticipated by Le Bolt.

Le Bolt discloses a disposable diaper. As shown in Figures 1-3, the diaper includes two long strips of self-sealing adhesive 17 applied to the outer surface of the diaper so they cannot contact the baby's skin and two small areas of self-sealing adhesive 18 located on the inside surface of the diaper. As shown in Figure 3, the two long strips of self-sealing adhesive 17 and the two small areas of self-sealing adhesive 18 cooperate together to fasten the diaper on a baby.

The appellants argue (brief, pp. 7-8) that Le Bolt does not disclose a diaper which includes an adhesive which is configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body. We agree. As set forth previously, the limitation that the adhesive be configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body is a structural limitation in that it requires placement of the adhesive in a location on the bodyfacing surface of the diaper such that it contacts the wearer's body when the diaper is in use (i.e., on the wearer). Clearly, when Le Bolt's diaper is in use, no adhesive contacts the wearer's body. Accordingly, Le Bolt's adhesive areas are not configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body.

For the reasons set forth above all the limitations of claims 19 and 31 are not disclosed in Le Bolt, consequently, the decision of the examiner to reject claims 19 and 31 under 35 U.S.C. § 102(b) as being anticipated by Le Bolt is reversed.

The anticipation rejection based upon Polski

We will not sustain the rejection of claims 19 to 23 and 31 under 35 U.S.C. §

102(b) as being anticipated by Polski.

Polski's invention is concerned with a side closure system for disposable diapers comprised of two separate fastening systems, one adhesive type fastening system and one nonadhesive fastening system. Figure 2 shows the disposable diaper as it would appear while being worn. As shown in Figures 1 and 2, the disposable diaper 10 is a three-layer composite including a liquid permeable, user contacting top sheet 12, a liquid-impervious outer shell or back sheet 14 and an absorbent layer 16. At the back 18 of the diaper are corners 20 that overlap with corresponding corners 21 at the front panel 22 of the diaper when the diaper is worn. On the top sheet side of the diaper at each of the corners 20 is located a release treated, non-woven release tab 24 and on the outer shell or backsheet 14 at the front corners 21 of the diaper 10 are mechanical type fasteners 26. Each of the release treated non-woven tabs 24, at the back corners 20, will be able to contact and engage with one of the mechanical fasteners 26 at the front corners 21 of the diaper 10. Fastening tabs 28 are located at the back sheet 18 of the diaper 10. During non-use the tabs 28 would be located on the non-woven release treated tabs 24. When in use, the fastening tabs 28 would be removed from the release treated non-woven tabs 24 and attached to a front panel 22 of the diaper back sheet 18. Generally, the diaper front panel 22 is provided with a landing or frontal strip 25 which reinforces the diaper at the waist portion of the front diaper panel 22, allowing removal and replacement of the fastening tab as necessary.

*4 The appellants argue (brief, pp. 8-10) that Polski does not disclose a diaper which includes an adhesive which is configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body. We agree. As set forth above, the limitation that the adhesive be configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body is a structural limitation in that it requires placement of the adhesive in a location on the bodyfacing surface of the diaper such that it contacts the wearer's body when the diaper is in use (i.e., on the wearer). Clearly, when Polski's diaper is in use, no adhesive contacts the wearer's body. Accordingly, Polski's adhesive is not configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body.

For the reasons set forth above all the limitations of claims 19 to 23 and 31 are not disclosed in Polski, consequently, the decision of the examiner to reject claims 19 to 23 and 31 under 35 U.S.C. § 102(b) as being anticipated by Polski is reversed.

The obviousness rejections based upon Takemoto

We will not sustain the rejection of claims 1 to 18, 24 to 28 and 30 under 35 U.S.C. § 103 as being unpatentable over Takemoto.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established by presenting evidence that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed combination or other modification. See In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Furthermore, the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the

claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

As set forth above, all the limitations of independent claims 1, 17 and 19 are not disclosed in Takemoto since Takemoto's adhesive patches 24 are not configured to contact the wearer's body in use to at least temporarily secure the bodyfacing surface of the diaper directly to the wearer's body. In the rejections under 35 U.S.C. § 103, the examiner has not cited any evidence that would have led a person having ordinary skill in the art to modify Takemoto's diaper to arrive at the claimed invention. Accordingly, the decision of the examiner to reject claims 1 to 18, 24 to 28 and 30 under 35 U.S.C. § 103 as being unpatentable over Takemoto is reversed.

CONCLUSION

*5 To summarize, the decision of the examiner to reject claims 1 to 31 is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

IAN A. CALVERT

Administrative Patent Judge

JOHN P. McQUADE

Administrative Patent Judge

JEFFREY V. NASE

Administrative Patent Judge

2001 WL 1176515 (Bd.Pat.App & Interf.)

END OF DOCUMENT

Westlaw.
2005 WL 1181897 (Bd.Pat.App & Interf.)
(Cite as: 2005 WL 1181897 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE TOSHIO YAGIHASHI AND SHUN-ICHI SATO
Appeal No. 2004-2289
Application No. 09/825,337
Heard: April 21, 2005

Sughrue, Mion, Zinn, MacPeak & Seas

2100 Pennsylvania Ave., N.W.

Washington, DC 20037-3202

Before KRASS, BLANKENSHIP, and NAPPI

Administrative Patent Judges

NAPPI

Administrative Patent Judge

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 of the final rejection of claims 1 through 15 which constitute all the claims remaining in the application. For the reasons stated infra we will not sustain the examiner's rejection of these claims.

THE INVENTION

The invention relates to a system and method to use a sales network in which a web site allows consumers to purchase a specific item from one seller to purchase relevant items from another seller. For example, a purchaser of a portable electronic device may also buy a case from another seller. See page 1 of appellants' specification.

Claim 1 is representative of the invention and is reproduced below:

1. A commercial sales method via a network, comprising:

a step of registering in advance a specific-item catalogue relating to a specific item and a relevant-item catalogue for items relevant to the specific item in a home page on the WWW;

a step, performed by a purchaser, of viewing both the specific-item catalogue and the relevant-item catalogue on the home-page via the network through a purchaser terminal, and sending a purchase request to a relevant-item seller selling the items relevant to the specific item by designating one of the items relevant to the specific item so as to purchase the designated item;

a step, performed by the relevant-item seller, of delivering a product of the designated item to the purchaser according to the purchase request;

a step, performed by the relevant-item seller, of informing a settlement computer of sales data of the purchased item; and

a step, performed by the settlement computer, of transferring a sales commission from a sales account of the relevant-item seller to a sales account of a specific-item seller selling the specific item, the specific item seller being different from the relevant-item seller,

wherein the specific-item catalogue and the relevant-item catalogue each comprise information about the item in addition to a link.

THE REFERENCES

The references relied upon by the examiner are:

Bezos et al. (Bezos)	6,029,141	Feb. 22, 2000
Tavor et al. (Tavor)	6,070,149	May 30, 2000

THE REJECTIONS AT ISSUE

Claims 1 through 15 stand rejected under 35 U.S.C. § 103 as being obvious over Tavor in view of Bezos. Throughout the opinion we make reference to the briefs and the answer for the respective details thereof.

OPINION

*2 We have carefully considered the subject matter on appeal, the rejection advanced by the examiner and the evidence of obviousness relied upon by the examiner as support for the rejection. We have, likewise, reviewed and taken into consideration, in reaching our decision, appellants' arguments set forth in the briefs along with the examiner's rationale in support of the rejection and arguments in rebuttal set forth in the examiner's answer.

With full consideration being given to the subject matter on appeal, the examiner's rejection and the arguments of appellants and the examiner, for the reasons stated infra, we will not sustain the examiner's rejection of claims 1 through 15 under 35 U.S.C. § 103.

Appellants assert on page 6 of the brief:

Tavor is directed to a virtual sales representative which guides a purchaser through successive departmental web pages of a single vendor, thus facilitating the purchaser's online shopping experience. Tavor discloses only one vendor and fails to teach or suggest a second vendor (footnote omitted).

On page 7 of the brief, Appellants assert:

Bezos is directed to an internet-based customer referral system, in which links to a vendor's webpage are provided on an "associate's" webpage. According to Bezos, an "associate" may be, for example, an internet-based product reviewer or a recommendation service. Bezos fails to teach or suggest that the "associate" could be a product-vendor. Like Tavor, Bezos discloses only one vendor.

Further, Appellants argue:

Each of the claims also requires transferring a sales commission from a sales account of one vendor to a sales account of a second vendor. Neither of these

features recited in claims 1, 5, 9 and 14 are found in Bezos. As mentioned, each of these features requires and pre-assumes a system including at least two vendors. Bezos specifically discloses that the website of the "associate" is an information dissemination system including marketing information such as product reviews or recommendations.

The examiner in response, on pages 6 and 7 of the answer, states:

Regarding the argument that Tavor et al. fail to disclose all of the features recited by the claims of Group I, the argument is irrelevant, hence spurious, as the same shortcomings alleged by appellant were specifically pointed out in, and addressed by, the rejection. Therefore, the argument merely restates the facts admitted by the rejection, without pointing out any supposed or alleged error in the rejection, thus, should be disregarded.

Regarding the argument that Bezos et al. fail to remedy the deficiencies of Tavor et al. because Bezos et al. disclose only a single "vendor," since the second entity they disclose is characterized by them as an "associate" rather than literally/explicitly as a second "vendor," Bezos et al. indeed disclose a first vendor and a second vendor... Inasmuch as an "associate" is commonly defined and accepted to mean a person united with another or others in an act, an enterprise, or a business, and, as admitted by appellant, the first entity/vendor of Bezos et al. is indeed engaged in the act of selling, any "associate" of that vendor is then, by definition, united with the first entity/vendor in that act of selling. Therefore, the "associate" is a second entity engaged in the act of selling, hence, a second vendor. (emphasis original, citations omitted).

*3 We disagree with the examiner's rationale. Claim 9 includes the limitations of "relevant-item catalogue information relating to an item relevant to the specific item;" "a purchaser terminal configured to enable a user to view both the specific-item catalogue information and the relevant-item catalogue information on the homepage, and to send a purchase request to a relevant-item seller module by designating the item relevant to the specific item so as to purchase the designated item" and "wherein the specific item is sold by the specific-item seller module, and the relevant-item seller module is different from the specific-item seller module." Independent claims 1, 5 and 14 contain similar limitations. Thus, we find that the scope of the independent claims includes the limitations that the specific-item seller sells the specific item and the relevant item is sold by a different seller. We disagree with the appellants' statement, on page 7 of the brief, that Bezos fails to teach that the "associate" could be a product vendor. We find that Bezos does teach that the "associate" sells items in that the associate presents items for sale on the associate's website. See, for example, figure 10A which depicts a sample of an associate's website. However, we do not find that Bezos teaches that the specific-item is sold by one seller and the relevant item is sold by another seller. We find that Bezos teaches that the items sold by the associate are all routed through a single merchant, however, we find no disclosure that the items sold by the associate can be routed through more than one merchant or that the associate acts as the merchant for some of the items sold. Thus, we find that the combination of Tavor and Bezos does not teach all of the limitations of independent claims 1, 5, 9 and 14. Accordingly, we will not sustain the examiner's rejection of claims 1-15.

CONCLUSION

We will not sustain the examiner's rejection of claims 1 through 15 under 35 U.S.C. § 103.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

ERROL A. KRASS

Administrative Patent Judge

HOWARD B. BLANKENSHIP

Administrative Patent Judge

ROBERT E. NAPPI

Administrative Patent Judge

2005 WL 1181897 (Bd.Pat.App & Interf.)

END OF DOCUMENT

1997 WL 1909599 (Bd.Pat.App & Interf.)
(Cite as: 1997 WL 1909599 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE NORMA F. ROSENHAIN
Appeal No. 97-0672
Application No. 08/329,086 [FN1]

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

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ON BRIEF

DECISION ON APPEAL

This is an appeal from the decision of the examiner finally rejecting claims 1 through 11, which constitute all of the claims of record in the application.

The appellant's invention is directed to a two piece utensil holding container. The subject matter before us on appeal is illustrated by reference to claim 1, which reads as follows:

1. A two-piece utensil holding container comprising:
a rigid inner member having a body portion with an interior and exterior surface, an open top and a closed bottom;
a supple, sleeve member mounted about the exterior surface of the body portion of the inner member, said sleeve member having an inner and outer surface, said outer surface of said sleeve member having a three-dimensional decorative

image molded thereon, said decorative image including a portion defining at least one gripping member, which is configured to engage and removably hold a utensil.

THE REFERENCES

The references relied upon by the examiner to support the final rejection are:

Zent et al. (Zent)	2,484,776	Oct. 11, 1949
Engvall	5,178,354	Jan. 12, 1993
United Kingdom Design Patent (Chan)	2,023,013	Feb. 22, 1993

THE REJECTION

Claims 1-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Chan in view of Engvall and Zent.

The rejection is explained in the Examiner's Answer.

The opposing viewpoints of the appellant are set forth in the Brief.

OPINION

The test for obviousness is what the combined teachings of the prior art would have suggested to one of ordinary skill in the art. See In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In establishing a prima facie case of obviousness under 35 U.S.C. § 103, it is incumbent upon the examiner to provide a reason why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. See Ex parte Clapp, 227 USPQ 972, 973 (BPAI 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from the appellant's disclosure. See, for example, Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1052, 5 USPQ2d 1434, 1052 (Fed. Cir.), cert. denied, 488 U.S. 825 (1988).

*2 The appellant's invention is directed to a cup that is configured to retain a utensil, such as a toothbrush, upon its decorative exterior surface. As defined in independent claim 1, it comprises a two-piece container having a rigid inner member and a supple sleeve mounted about the exterior surface of the inner member. A three-dimensional decorative image is molded on the outer surface of the sleeve, and this decorative image includes "a portion defining at least one gripping member, which is configured to engage and removably hold a utensil."

It is the examiner's position that Chan shows the claimed structure except for the gripping member, but that it would have been obvious to one of ordinary skill in the art to add such a feature in view of the teachings of Engvall and Zent.

Chan discloses a design which is described as "a mug with a detachable outer coating." There is no clue as to whether the outer coating is "a supple, sleeve member" as is required by the claim. Although the drawings are barely discernible, it is clear that Chan has no structure which could function as a ""gripping member ... configured to engage and removably hold a utensil." Engvall discloses an aerosol dispenser that has a gripping member attached to its side to removably hold a tube through which the aerosol material can be dispensed. Zent discloses a

decorative cover for a bottle which comprises a three-dimensional decorative figure. The decorative figure has bendable arms, to one of which is attached a candy cane. There is no explicit teaching that the arms be used to removably hold a receptacle, nor is it apparent that they are capable of doing so.

It is axiomatic that the mere fact that the prior art structure could be modified does not make such a modification obvious unless the prior art suggests the desirability of doing so. See In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). We fail to perceive any teaching, suggestion or incentive in either of the secondary references which would have suggested to one of ordinary skill in the art the desirability of modifying the Chan device so that it can removably hold a utensil, much less doing so by means of a gripping member defined in the decorative image. While it could be concluded that Engvall would have suggested to one of ordinary skill in the art that a utensil holder be installed on the outside surface of the Chan device, it would not have motivated the artisan to define the holder by a portion of the decorative image, as is required by the claims. As for Zent, we are at a loss to appreciate what this reference adds to the rejection.

It therefore is our conclusion that the combined teachings of the three applied references fail to establish a prima facie case of obviousness with regard to the subject matter of claim 1. This being the case, we will not sustain the rejection of claim 1 or, it follows, of dependent claims 2-11.

*3 The decision of the examiner is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

IAN A. CALVERT

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Senior Administrative Patent Judge

NEAL E. ABRAMS

Administrative Patent Judge

FN1. Application for patent filed October 25, 1994.

JoAnne

Appeal No. 97-0672

Application No. 08/329,086

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APJ McCANDLISH

REVERSED

Prepared: July 18, 2000

1997 WL 1909599 (Bd.Pat.App & Interf.)

END OF DOCUMENT